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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,296	09/29/2003	Ronan Thornton	P1818 US (2650/106)	4107

7590 04/19/2005

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EXAMINER	
PRONE, CHRISTOPHER D	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No.	Applicant(s)	
	10/674,296	THORNTON ET AL.	
	Examiner	Art Unit	
	Christopher D Prone	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *1-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/29/03 & 3/30/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-16, drawn to a method of applying a drug-polymer coating on a stent, classified in class 623, subclass 1.46.

II. Claims 17-34, drawn to drug-polymer coated stent, classified in class 623, subclass 1.11.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by a materially different process such as rolling or wrapping the stent in the drug-polymer instead of dipping it.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: a drug-polymer coated stent.

Species 1 shown in figure 2a

Species 2 shown in figure 2b

Species 3 shown in figure 2c

Species 4 shown in figure 2d

Species 5 shown in figure 2e

Upon election from the above species a further election is required among the following subspecies:

Species 6 shown in figure 4a

Species 7 shown in figure 4b

Species 8 shown in figure 4c

Species 9 shown in figure 4d

Species 10 shown in figure 4e

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are considered generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and **a listing of all claims readable thereon**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Catherine Maresh on 4/11/05 a provisional election was made without traverse to prosecute the invention of group 2, species 2, and species 6, claims 17-38. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-16 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17-25 and 28-38 are rejected under 35 U.S.C. 102(b) as being anticipated by United States Patent 5,380,299 Fearnot.

In regards to claims 17 and 25, Fearnot discloses the same invention being a catheter described in column 1 on lines 11-21 and a drug-polymer coated stent, comprising: a stent framework referenced as element 12, a laminated drug-polymer coating disposed on the stent framework, the laminated drug-polymer coating including a plurality of thin drug-polymer layers, wherein the thin drug-polymer layers include a first therapeutic agent and a cured first polymer shown in figure 5 and described in column 2 on lines 10-25 of Fearnot.

In regards to claims 18, 19, 28, and 29, Fearnot discloses the same invention wherein the stent framework comprises a metallic base made of nitinol described in column 3 on lines 7-22.

In regards to claims 20, 24, 30, and 34, Fearnot discloses the same invention wherein the first and second therapeutic agents are selected from the group consisting of rapamycin, a rapamycin derivative, a rapamycin analogue, camptothecin,

dexamethasone, 5-fluorouracil, a bioactive agent, a pharmaceutical drug, a therapeutic substance, and a combination thereof described in column 1 on lines 60-68 of Fearnot.

In regards to claims 21 and 31, Fearnot discloses the same invention wherein a concentration of the first therapeutic agent is modulated to provide a predetermined drug-release profile described in column 2 on lines 18-22 of Fearnot.

In regards to claims 22, 23, 32, and 33, Fearnot discloses the same invention comprising: at least one thin barrier layer positioned between one or more thin drug-polymer layers, wherein the thin barrier layer includes a cured second polymer and a second therapeutic agent shown in figure 5 and described in column 2 on lines 10-25 of Fearnot.

In regards to claim 35 Fearnot discloses the same invention comprising a drug-polymer coated stent including a laminated drug-polymer coating having a plurality of thin drug-polymer layers, wherein the thin drug-polymer layers include at least one therapeutic agent and a cured first polymer described in column 2 in lines 10-25; wherein it is inherent that the invention of Fearnot comprises inserting a drug-polymer coated stent within a vessel of a body and eluting at least one therapeutic agent from the laminated drug-polymer coating into the body

In regards to claim 36, Fearnot discloses the same invention wherein the drug-polymer coated stent includes at least one thin barrier layer positioned between one or more thin drug-polymer layers, wherein the thin barrier layer includes a cured second polymer shown in figure 5 and described in column 2 on lines 10-25 of Fearnot.

In regards to claim 37, Fearnot discloses the same invention wherein the thin barrier layers control an elution rate of at least one therapeutic agent described in column 2 on lines 18-22 of Fearnot.

In regards to claim 38, Fearnot discloses the same invention comprising selecting the cured first polymer and the cured second polymer based on a predetermined elution rate of at least one therapeutic agent described in column 2 on lines 18-22 of Fearnot.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 26 and 27 are rejected under 35 U.S.C. 103 as being unpatentable over United States Patent 5,380,299 Fearnot in view of United States Patent 6,251,136 Guruwaiya.

Fearnot discloses the invention substantially as claimed being a catheter and drug-polymer coated stent. However, Fearnot does not disclose use of an inflation balloon and a sheath.

Guruwaiya teaches the use of a balloon catheter with a sheath in the same field of endeavor for the purpose of securing the stent to the catheter during delivery and securing the stent to the operating site after delivery.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the sheath and balloon catheter of Guruwaiya with drug-polymer coated stent of Fearnot in order to provide a more secure delivery device for the stent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D Prone whose telephone number is (571) 272-6085. The examiner can normally be reached on Monday Through Fri 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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